



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2012-N-0536; FDA-2020-N-1307; FDA-2014-N-1048; FDA-2021-N-0356; FDA-2011-D-0147; FDA-2018-N-1857; FDA-2021-N-0341; and FDA-2015-N-1837]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Table 1--List of Information Collections Approved By OMB

Title of Collection	OMB Control Number	Date Approval Expires
Medical Device User Fee Cover Sheet and Device Facility User Fee Cover Sheet	0910-0511	10/31/2024
Examination of Secondary Claim Disclosures and Biosimilar Disclosures in Prescription Drug Promotional Materials	0910-0902	10/31/2024
Medical Device Labeling Regulations	0910-0485	11/30/2024
Establishment and Operation of Clinical Trial Data Monitoring Committees	0910-0581	11/30/2024
Reports Intended to Demonstrate the Substantial Equivalence of a New Tobacco Product	0910-0673	11/30/2024
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food and Food for Animals	0910-0751	11/30/2024
Federal-State Regulatory Program Standards	0910-0760	11/30/2024
Electronic User Fee Payment Form	0910-0805	11/30/2024

Dated: December 27, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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